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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,928	07/15/2003	Richard A. Terwilliger	WORLD-01000USB	6815
23910	7590	01/26/2005		
FLIESLER MEYER, LLP FOUR EMBARCADERO CENTER SUITE 400 SAN FRANCISCO, CA 94111			EXAMINER VENIAMINOV, NIKITA R	
			ART UNIT 3736	PAPER NUMBER

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/619,928

Applicant(s)

TERWILLIGER ET AL.

Examiner

Nikita R Veniaminov

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 and 20 is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-14, 16, 17, 19 and 21-29 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. **Claim 7** is objected to because of the following informalities: The phrase "specifying" in line 3 should read "specifying". Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. **Claims 1, 5, 14, 16, 17, 19, 23-25 and 29** are rejected under 35 U.S.C. 102(e) as being anticipated by Drobnik et al. (US 2004/0158118). Drobnik et al. ('8118) teach a prescription method of treating tissue comprising the steps of:

Claim 1 (independent)

accepting a tissue treatment plan for the tissue to be treated (page 2 [0016]. Examiner states that constructed by physician treatment plan should be accepted in order to execute said plan), which treatment plan specifies a number and spacing of treatment seeds to be provided in each of a plurality of treatment strands (page 1[0002] and page 2[0016]); creating the plurality of treatment strands according to said tissue treatment plan (page 1 [0002] and page 2[0017]); and

wherein at least two of the plurality of treatment strands have a custom distal end spacing between the end of each treatment strand and the adjacent treatment seed (page 3 [0029, lines 5-7]);

Claim 5

The method of claim 1, further comprising the steps of: aligning the plurality of treatment strands in a template (page 1[0003].

Claim 14 (independent)

A therapeutic device comprising:

a plurality of seed strands, each having a length with a distal end (page 1[0002]) and page 2[0019]);

a plurality of seeds provided along the length of each of the seed strand (page 2[0016]);

the plurality of seeds being provided at spaced intervals along the length of each of the seed strands (page 2[0016]); and

custom end spacings according to a treatment plan provided between the seed located adjacent to the distal end of each of said seed strands and the distal end of each said seed strand (page 3[0029, lines 5-7]);

Claim 16

The device in accordance with claim 14, further comprising:

at least two of said plurality of seed strands have different custom end spacings of different lengths (page 3[0029]).

Claim 17 (independent)

accepting a tissue treatment plan for the tissue to be treated (page 2 [0016]), which treatment plan specifies a number and spacing of treatment seeds to be provided in the treatment plan and which specifies custom end spacings between an end seed in a strand and the end of the strand (page 2 [0018]); and creating a treatment strand according to the plan (page 3 [0029]).

Claim 19 (independent)

A prescription method of treating tissue comprising the steps of:
first accepting a tissue treatment plan for the tissue to be treated (page 2 [0016]. Examiner states that constructed by physician treatment plan should be accepted in order to execute said plan), said treatment plan specifying a number and spacing of a plurality of treatment seeds for each of a plurality of respective treatment seed strands (page 1[0002] and page 2[0016]);
second creating the plurality of treatment seed strands from a material (page 1 [0002] and page 2[0017]); and
third providing a custom distal end spacing on each of the plurality of treatment seed strands (page 3 [0029, lines 5-7]).

Claim 23 (independent)

A prescription method of treating tissue comprising the steps of:

first accepting a tissue treatment plan for the tissue to be treated (page 2 [0016]. Examiner states that constructed by physician treatment plan should be accepted in order to execute said plan), said treatment plan specifying a number and spacing of a plurality of treatment seeds for each of a plurality of respective treatment seed strands (page 1[0002] and page 2[0016]);

second creating the plurality of treatment seed strands from a material (page 3 [0029]); and

third providing a custom distal end spacing on each of the plurality of treatment seed strands, wherein at least two of said plurality of treatment seed strands have different custom end spacing (page 3 [0029, line s5-7]).

Claim 24 (independent)

A prescription method of treating tissue comprising the steps of:

first accepting a tissue treatment plan for the tissue to be treated (page 2 [0016]. Examiner states that constructed by physician treatment plan should be accepted in order to execute said plan), said treatment plan specifying a number and spacing of a plurality of treatment seeds for each of a plurality of respective treatment seed strands;

second creating the plurality of treatment seed strands from a material (page 3 [0029]); and

third providing a custom distal end spacing on each of the plurality of treatment seed strands (page 3 [0029, line s5-7]), wherein the custom distal end spacing is

determined by the treatment plan, and the custom distal end spacing allows a health care professional to insert each of the plurality of treatment seed strands to a uniform depth in the tissue to be treated (Examiner states that the phrase “the custom distal end spacing is determined by the treatment plan, and the custom distal end spacing allows a health care professional to insert each of the plurality of treatment seed strands to a uniform depth in the tissue to be treated” does not positively recite method step, thus the method of Drobnik et al. ('8118) meets the method steps set forth in claim 24).

Claim 25 (independent)

A method of treating a patient with a plurality of treatment strands wherein each of said plurality of treatment strands has a plurality of spaced seeds and a custom end spacing between a distal end seed of the treatment strand and a distal end of the treatment strand (page 3 [0029, line s5-7]), the method comprising the steps of:

implanting a first treatment strand at a desired location at a depth (page 1[0002]);

and

implanting the remainder of the plurality of treatment strands at a plurality of respective desired locations to the depth of the first strand (page 1[002]),

wherein each distal end seed of each of said plurality of treatment strands can be at a different depth (Examiner states the phrase “can be at different depth” does

not require particular limitation, thus the method of Drobnik et al. ('8118) meets the method steps set forth in claim 25).

Claim 29 (independent)

A therapeutic device comprising:

a plurality of seed strands (page 1[0002]), each having a length with a distal end (page 3[0027]);

a plurality of seeds provided along the length of each of the seeds strands (page 1[0002]);

the plurality of seeds being provided at spaced intervals along the length of each of the seed strands (page 1[0002]); and

custom end spacings according to a treatment plan provided between the seed located adjacent to the distal end of each of said seed strands and the distal end of each said seed strand, wherein at least two of said plurality of seed strands have different said custom end spacings of different lengths (page 1[0002] and page 3[0029]).

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Drobnik et al. (US 2004/0158118), as applied to claim 5 above, in view of Horowitz (US 4,815,449).

Drobnik et al. ('8118) teach a prescription method of treating tissue as described in paragraph 3 above, but they do not teach a method, wherein all of a plurality of treatment strands are the same length.

Horowitz ('449) teaches a method of treating tissue using a plurality of treatment strands having the same length (Figure 7 and column 4, lines 38-46).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the plurality of treatment strands having the same length of Horowitz ('449) in the method of Drobnik et al. ('8118) to provide desired radiation treatment at multiple locations at different depth in the diseased tissue, as taught by Horowitz ('449).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. **Claims 1-4, 7, 9-13, 21, 22 and 26-28** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 17, 18 and 25** of copending Application No.

10/415,715 in view of Drobnik et al. (US 2004/0158118). Claims of the copending Application disclose a method for making a radioactive strand, but they do not disclose a prescription method of treating tissue comprising the steps of accepting a tissue treatment plan for the tissue to be treated, which treatment plan specifies a number and spacing of treatment seeds to be provided in each of a plurality of treatment strands.

Drobnik et al. ('8118) teach a prescription method of treating tissue comprising the steps of: accepting a tissue treatment plan for the tissue to be treated (page 2 [0016]), which treatment plan specifies a number and spacing of treatment seeds to be provided in each of a plurality of treatment strands (page 1[0002]); creating

the plurality of treatment strands according to said tissue treatment plan (page 3 [0029]); and wherein at least two of the plurality of treatment strands have a custom distal end spacing between the end of each treatment strand and the adjacent treatment seed (page 3 [0029]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of treating tissue of Drobnik et al. ('8118) having the steps of creating treatment seed strands by the method for making the radioactive member disclosed in the copending Application to provide custom seed strands specified by the treatment plan, as taught by Drobnik et al. ('8118).

This is a provisional obviousness-type double patenting rejection.

Allowable Subject Matter

7. **Claims 18 and 20** are allowed.
8. **Claim 8** is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
9. The following is a statement of reasons for the indication of allowable subject matter:

None of the prior art, either alone or in combination, teaches or suggests (**Claim 8**) a prescription method of treating tissue, as claimed, wherein a first accepting step comprises accepting a tissue treatment plan created with the use of a computer program.

None of the prior art, either alone or in combination, teaches or suggests **(Claim 18)** a method of treating a patient with a plurality of treatment strands, as claimed, comprising a step of implanting the remainder of the plurality of seed strands at a plurality of respective desired locations to the depth of a first strand.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hoskins et al. ('753); Slater et al. ('851); Drobnik et al. ('8117) and Yoshizumi ('525).

Response to Arguments

11. Applicant's arguments, see **RESPONSE TO OFFICE ACTION**, filed on 09/23/2004, with respect to the rejection(s) of claim(s) 1-6, 14 and 15 under 35 USC 112, second paragraph; 35 USC 102(b), 102(e) and USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Drobnik et al. (US 2004/0158118) and Horowitz (US 4,815,449).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (571) 272-4735. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nikita R Veniaminov
Examiner
Art Unit 3736

December 17, 2004.



SAMUEL G. GILBERT
PRIMARY EXAMINER